

90-DAY RESPONSE

DCI Number: GDCI-128997-1598

Data Call-In Information

| | |
|--------------------------|----------------------------------|
| Company Name | SHARDA CROP CHEM LIMITED |
| Company Address | P.O. Box 640 HOCKESSIN, DE 19707 |
| DCI Type | Generic |
| Issued Date | 09/14/2017 |
| 90 Day Response Deadline | 12/23/2017 |
| CRM Information | Kettl, Brian |
| Chemical Name | Tebuconazole |
| Chemical Number | 128997 |

90-Day Response Information

| | |
|-----------------|---------------------|
| Tracking Number | CDX_DCI_2017_001651 |
|-----------------|---------------------|

DCI Level Documents

| File Name | File Type | MRID | CBI | Submitted Date |
|--|-------------------------|------|-----|----------------|
| Sharda Cropchem Agent Letter 13Feb2014.pdf | Submission Cover Letter | N.A. | N | 12/22/2017 |

EPA Product Registration Number(s)

| | |
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| 82633 1 | I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." |
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Guideline Requirement Number(s)

Guideline Requirement Number - 835.1110

| | |
|------------------------|--|
| Study Title | Activated sludge sorption isotherm |
| Protocol | N |
| Target Submission Date | 09/14/2018 |
| Use Pattern | A; BB; C; Q; X |
| Test Substance | TGAI |
| Time Frame | 12 month(s) |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 34. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003 . |
| Registrant Response | Offer to Cost Share |

Uploaded Documents

| File Name | File Type | MRID | CBI | Submitted Date |
|-----------------------------------|---|------|-----|----------------|
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | N.A. | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | N.A. | N | 12/22/2017 |

Guideline Requirement Number - 835.3110

| | |
|------------------------|------------------------|
| Study Title | Ready biodegradability |
| Protocol | N |
| Target Submission Date | 09/14/2018 |
| Use Pattern | A; BB; C; Q; X |

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|--|--|------|-----|----------------|
| Test Substance | TGAi | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 33. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test. | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 835.3220 | | | | |
| Study T t e | Porous pot test | | | |
| Protoco | N | | | |
| Target Subm ss on Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGAi | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 32. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test. | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 835.3240 | | | | |
| Study T t e | Simulation Test-Aerobic Sewage Treatment-Activated Sludge | | | |
| Protoco | N | | | |
| Target Subm ss on Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGAi | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 31. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test. | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |

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|--|--|------|-----|----------------|
| Guideline Requirement Number - 835.3280 | | | | |
| Study Title | Simulation Tests to Assess the Biodegradability of Chemicals | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 30. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.2100 | | | | |
| Study Title | Avian acute oral toxicity test | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 14. This study is required only in support of conventional uses. 23. Only passerine species toxicity data are required. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.3020 | | | | |
| Study Title | Honey bee acute contact toxicity | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 8. Tier 1 study. USEPA. 2012a. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019 14. This study is required only in support of conventional uses. 21. See also OECD 214: OECD.1998b. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en | | | |

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|---|---|---------------------|-----|----------------|
| Reg strant Response | | Offer to Cost Share | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.3030 | | | | |
| Study T t e | Honey bee toxicity of residues on foliage | | | |
| Protoco | Y | | | |
| Target Subm ss on Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | <p>2. USEPA. 2012b. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018.</p> <p>9. Tier 1 study. Guideline 850.3030 data are required when the product formulation contains one or more active ingredient(s) having an acute LD50 of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.</p> <p>14. This study is required only in support of conventional uses.</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p> | | | |
| Reg strant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.3040 | | | | |
| Study T t e | Field testing for pollinators | | | |
| Protoco | Y | | | |
| Target Subm ss on Date | 09/14/2019 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| T me Frame | 24 month(s) | | | |
| Footnote(s) | <p>1. USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.</p> <p>3. Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. This study is required only in support of conventional uses.</p> <p>20. See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p> | | | |
| Reg strant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |

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|--|--|------|-----|----------------|
| Guideline Requirement Number - 850.3300 | | | | |
| Study Title | Modified Activated Sludge, Respiration Inhibition Test | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA1 | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | <p>15. This study is required only in support of antimicrobial uses.</p> <p>18. The results of the Activated Sludge, Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests are required. If the ASRI test results in an EC50 of less than or equal to 20 mg/L, then either the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, GLN 835.3280, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test results in an EC50 greater than 20 mg/L, then the registrant is required to conduct either the (i) Ready Biodegradability, GLN 835.3110, (ii) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (iii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iv) the Porous Pot Test. If the Ready Biodegradability Study is conducted and passes, then no further testing is required. If, however, the pesticide fails the Ready Biodegradability study, then the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot Test is required.</p> <p>24. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en</p> <p>29. EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021.</p> | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.4100 | | | | |
| Study Title | Seedling Emergence and Seedling Growth | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | <p>6. Tier 2 data on monocots are required.</p> <p>14. This study is required only in support of conventional uses.</p> | | | |
| Registrant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - 850.4150 | | | | |
| Study Title | Vegetative Vigor | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |

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|--|--|------|-----|----------------|
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 7. Tier 2 data on dicots and monocots are required. 14. This study is required only in support of conventional uses. | | | |
| Registrant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | N.A. | N | 12/22/2017 |
| Guideline Requirement Number - 850.4500 | | | | |
| Study Title | Algal Toxicity | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA, TEP | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 16. This study is required in support of both antimicrobial and conventional uses. 25. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028 . 38. Algal toxicity data required on two species of non-vascular plants (freshwater and marine diatoms). | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | N.A. | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | N.A. | N | 12/22/2017 |
| Guideline Requirement Number - 850.4550 | | | | |
| Study Title | Cyanobacteria (Anabaena flos-aquae) Toxicity | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA, TEP | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 16. This study is required in support of both antimicrobial and conventional uses. 25. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028 . | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | N.A. | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | N.A. | N | 12/22/2017 |
| Guideline Requirement Number - 850.6100 | | | | |
| Study Title | Environmental Chemistry Methods and Associated Independent Laboratory Validation | | | |

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|--|---|------|-----|----------------|
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGAI | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 14. This study is required only in support of conventional uses. 35. ECMILV needed for soil and water. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - 875.1200 | | | | |
| Study Type | Dermal exposure--Indoor | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 19. The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - 875.1400 | | | | |
| Study Type | Inhalation exposure--indoor | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 15. This study is required only in support of antimicrobial uses. 19. The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |

| Guideline Requirement Number - 875.1700 | | | | |
|---|----------------|---|-----|----------------|
| Study Title | | Product Use Information | | |
| Protocol | | N | | |
| Target Submission Date | | 09/14/2018 | | |
| Use Pattern | | A; BB; C; Q; X | | |
| Test Substance | | TEP | | |
| Time Frame | | 12 month(s) | | |
| Footnote(s) | | 15. This study is required only in support of antimicrobial uses. 22. Product use data is needed to clarify uses (particularly the use of plastics in toys), application rates and wood retentions, and application equipment. | | |
| Registrant Response | | Waiver Request | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - 875.2100 | | | | |
| Study Title | | Foliar dislodgeable residue dissipation | | |
| Protocol | | N | | |
| Target Submission Date | | 09/14/2018 | | |
| Use Pattern | | A; BB; C; Q; X | | |
| Test Substance | | TEP | | |
| Time Frame | | 12 month(s) | | |
| Footnote(s) | | 14. This study is required only in support of conventional uses. 28. Foliar dislodgeable and turf transferrable residue dissipation data are required for post-application worker or residential exposure. | | |
| Registrant Response | | Waiver Request | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - 875.2300 | | | | |
| Study Title | | Indoor surface residue dissipation | | |
| Protocol | | Y | | |
| Target Submission Date | | 09/14/2018 | | |
| Use Pattern | | A; BB; C; Q; X | | |
| Test Substance | | TEP | | |
| Time Frame | | 12 month(s) | | |
| Footnote(s) | | 15. This study is required only in support of antimicrobial uses. 17. The wipe study is based on the need to assess dermal and incidental oral exposures to children (age 1-2) playing on pressure treated decks and play sets. 39. A waiver may be requested for all applications if a residue screening level default at 100% of the application rate does not trigger risk concerns. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | |
| Registrant Response | | Waiver Request | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |

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|---|---|------|-----|----------------|
| Justification of Waiver Request.pdf | Waiver Request | NA | N | 12/22/2017 |
| Guideline Requirement Number - SS-1196 | | | | |
| Study Title | Whole Sediment: Chronic toxicity to saltwater invertebrates | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2019 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 24 month(s) | | | |
| Footnote(s) | 16. This study is required in support of both antimicrobial and conventional uses. 37. Chronic sediment toxicity data required on one species of estuarine/marine amphipod. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - SS-1197 | | | | |
| Study Title | Whole Sediment: Chronic toxicity to freshwater invertebrates | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2019 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 24 month(s) | | | |
| Footnote(s) | 16. This study is required in support of both antimicrobial and conventional uses. 36. Chronic sediment toxicity data required on two freshwater species (an amphipod and a midge) in support of conventional uses. Only the freshwater amphipod data are required in support of antimicrobial uses. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - SS-1311 | | | | |
| Study Title | Honey bee adult acute oral toxicity | | | |
| Protocol | N | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 12 month(s) | | | |

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|--|--|------|-----|----------------|
| Footnote(s) | <p>10. Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en</p> <p>14. This study is required only in support of conventional uses.</p> | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - SS-1312 | | | | |
| Study T t e | Honey bee larvae acute oral toxicity | | | |
| Protoco | N | | | |
| Target Subm ss on Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGAI | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | <p>13. Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en</p> <p>14. This study is required only in support of conventional uses.</p> | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | NA | N | 12/22/2017 |
| Guideline Requirement Number - SS-1313 | | | | |
| Study T t e | Honey bee adult chronic oral toxicity | | | |
| Protoco | Y | | | |
| Target Subm ss on Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGAI | | | |
| T me Frame | 12 month(s) | | | |
| Footnote(s) | <p>11. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295</p> <p>14. This study is required only in support of conventional uses.</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p> | | | |
| Reg strant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | NA | Y | 12/22/2017 |

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|--|---|------|-----|----------------|
| Cover letter.pdf | General Correspondences | N A | N | 12/22/2017 |
| Guideline Requirement Number - SS-1314 | | | | |
| Study Title | Honey bee larvae chronic oral toxicity | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2018 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA | | | |
| Time Frame | 12 month(s) | | | |
| Footnote(s) | 12. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf 14. This study is required only in support of conventional uses. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | N A | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | N A | N | 12/22/2017 |
| Guideline Requirement Number - SS-1315 | | | | |
| Study Title | Semi-field testing for pollinators | | | |
| Protocol | Y | | | |
| Target Submission Date | 09/14/2019 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TGA, TEP | | | |
| Time Frame | 24 month(s) | | | |
| Footnote(s) | 5. Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment. 14. This study is required only in support of conventional uses. 26. Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (<i>Apis mellifera</i> L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en . 27. For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. | | | |
| Registrant Response | Offer to Cost Share | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Attempt to Cost Share 8570-32.pdf | Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data | N A | Y | 12/22/2017 |
| Cover letter.pdf | General Correspondences | N A | N | 12/22/2017 |
| Guideline Requirement Number - SS-1316 | | | | |
| Study Title | Field trial of residues in pollen and nectar | | | |
| Protocol | Y | | | |

| | | | | |
|-------------------------------------|---|------|-----|----------------|
| Target Submission Date | 09/14/2019 | | | |
| Use Pattern | A; BB; C; Q; X | | | |
| Test Substance | TEP | | | |
| Time Frame | 24 month(s) | | | |
| Footnote(s) | <p>4. Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. This study is required only in support of conventional uses.</p> <p>40. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar. 1) Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. 2) Consideration of the attractiveness of the selected crop to pollinators. 3) Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. 4) Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. 5) Consideration of the market proportion of the selected target crop(s).</p> | | | |
| Registrant Response | Waiver Request | | | |
| Uploaded Documents | | | | |
| File Name | File Type | MRID | CBI | Submitted Date |
| Justification of Waiver Request.pdf | Waiver Request | N.A. | N | 12/22/2017 |
| Submitter Information | | | | |
| Submitter | Anna Armstrong | | | |
| Submitted Date | 12/22/2017 | | | |